

OPERATIONAL GUIDELINES FOR OBSERVANCE OF GOOD PRACTICES IN CPCSEA

Experimentation on animals in course of medical research and education is covered by provisions of the Prevention of Cruelty to Animals Act, 1960 and the Rules under the Act of 1998 and 2001. This is enforced by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960. Under these provisions, the concerned establishments are required to get themselves registered with CPCSEA, get their Animal House Facilities inspected, and also get specific projects for research cleared by CPCSEA before commencing the research. Further, breeding and trade of animals for such experimentation are also regulated under these Rules.

GUIDELINES:

1. Main Activities

(a) Registration of establishments for Breeding of animals : Under Rule 3 of Breeding of and Experiments on Animals (Control and Supervision) Rules 1998.

(b) Registration of establishments for experiments on animals : Under Rule 4 of Breeding of and Experiments on Animals (Control and Supervision) Rules 1998.

(c) Approval of Animal House Facilities : Rule 5 (b) of Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 prescribes for inspections of such facilities before registration. Sub Rule (c) of Rule 5 as amended in 2001, provides for stipulating conditions at the time of registration. A specific condition regarding obtaining approval of Animal House Facilities, after detailed inspection before conduct of experiment may be imposed by the Member-Secretary at the time of registration.

(d) Permission of Committee for Conducting Experiments: Under Rule 8 of Breeding of and Experiments on Animals (Control and Supervision) Rules 1998.

(e) Recommendation for import under Rule 10 (e) of Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 as amended in 2001 :

2. Regulatory Mechanism :

2.1 Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) :- Constituted under the Provision of Section 15 of the Prevention of Cruelty to Animals (PCA) Act, 1960. The main mandate of the Committee is to ensure that animals are not subjected to unnecessary pain or suffering before, during or after performance of experiments on them. The CPCSEA functions within the ambit of the Act and the Rules for Breeding of and Experiments on Animals (Control & Supervision), 1998 as amended in February, 2001.

2.2 Sub-Committees of the CPCSEA: In exercise of the powers conferred under Section 15(A) of the Prevention of Cruelty to Animals Act 1960, which provides for constitution of Sub-Committees for exercising any power or discharging any duty of the Committee, the CPCSEA has constituted following 2 sub-committees for exercising some of its specific powers.

2.2.1 Sub-Committee on Large Animals (SCLA).

All projects involving experiments on large animals have to be approved by the Sub-Committee on Large Animals (SCLA). The Sub-Committee was re-constituted vide order No. 25/20/2003-AWD dated 2nd June, 2003.

2.2.2 Sub-Committee for selection of CPCSEA Nominees on Institutional Animals Ethics Committees

The CPCSEA in its meeting held on 11th July, 2003 decided to constitute a Sub-Committee for selection of CPCSEA Nominees on Institutional Animals Ethics Committees. (This has been communicated vide order No.25/39/2003-AWD dated 21st August, 2003).

The scope of this Sub-Committee is proposed to be enlarged to include selection of panel for conduct of Inspection Teams for Animal House Facilities. The selected panel would comprise of veterinarians, persons engaged in activities of Animal Welfare, and persons dealing with animal experimentations. The panels would be made zone wise. Besides, the Sub-Committee would also draw a panel of persons in-charge of some existing good Animal House Facilities to work in an advisory capacity.

2.3 Institutional Animal Ethics Committee (IAEC)

Every establishment constituted and operated in accordance with the procedures specified by the CPCSEA is required to constitute an Institutional Animal Ethics Committee.

As per Rule 13 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, every IAEC shall include; a biological scientist, two scientists from different biological disciplines, a

veterinarian involved in the care of animals, the scientist in charge of animals facility of the establishment concerned, a scientist from outside the institute, a non-scientific socially aware member and a representative or nominee of the CPCSEA. A specialist may be co-opted while reviewing special projects using hazardous agents such as radioactive substance and deadly microorganisms.

To each IAEC, a CPCSEA Nominee would be nominated and his presence would be necessary for every meeting. In order to ensure smooth functioning of the IAEC, there will be a link CPCSEA nominee, nominated for each IAEC who will participate in the meeting in event of inability of the regular CPCSEA nominee to attend such meeting.

The IAEC will scrutinize all project proposals for experimentation on animals. In case of small animals, it would give the final approval. In case of large animals, it would make its recommendation to SCLA which will be the final clearance authority.

2.4 Member Secretary, CPCSEA: As per Rules , Member Secretary, is responsible for registration of establishment engaged in Breeding of Animals and also in Experimentation on Animals. He is also responsible for causing the application for permission for conducting experiments to be brought before the CPCSEA and SCLA. Besides, he has also been authorized to constitute the Inspection Teams for inspection of Animal House Facilities, from the approved panel.

3. Standing time tables of meetings of the regulator/expert body:

(a) Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA):

The meetings are to take place quarterly. The schedule for the meetings will be 20th December, 20th March, 20th June, and 20th September every year. If the 20th happens to be a holiday, the meeting will be held the next working day.

(b) Sub-Committee on Large Animals (SCLA) : The meetings are to be held on 10th of every alternate month. If the 10th happens to be a holiday, the meeting will be held the next working day.

(c) Sub-Committee for selection of CPCSEA Nominees on Institutional Animals Ethics Committee : The meeting is proposed to be convened once in six months say in January and July.

(d) Institutional Animal Ethics Committee (IAEC): This committee functions within the research establishments and the standing time table of each IAEC would vary as per its needs.

(e) **Member Secretary, CPCSEA:** :- No requirement of standing time table.

Besides, in emergent situations, and to clear backlog, special meetings of the above regulatory bodies, may be convened with the approval of the Chair.

4. Nomination of Co-chair/Vice chair of the regulator/expert body for presiding over the meeting in the absence of the chair

(a) **Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA):**

As a standing arrangement, it is proposed to nominate JS or an equivalent in charge of Animal Welfare as Vice-Chair of the Committee. In the absence of JS or equivalent, the members present could nominate any member from amongst themselves to preside over proceedings of a meeting.

(b) **Sub-Committee on Large Animals (SCLA)**

and Sub-Committee for selection of CPCSEA Nominees:

The CPCSEA could make a provision that in absence of the Chair, in the above two Sub-Committees, the members present, would nominate any member from amongst themselves to preside over the proceedings of a meeting.

5. Creation of separate Web page: A web page of CPCSEA within the MOEF web site will be created with the help of NIC, displaying the following minimum information.

- (a) Ground Rules
- (b) Names of the Chair/Vice-chair of CPCSEA/ its Sub-Committees and the provision of nomination of any member among themselves to preside over the proceedings of the meeting in the absence of Chairman and Vice-Chairman.
- (c) Standing time table of the Committee meetings
- (d) A notice that, if necessary to consider all the listed cases the meeting would continue the following working day.
- (e) A notice that project proponents, if they wish to, may remain present at the time of the meeting to make a personal presentation.
- (f) Agenda for the next meeting
- (g) Status of all cases received in the Ministry

6. Ground Rules :

(i) **Registration of establishment for Breeding of animals & for experiments of animals:**

The Member-Secretary would take a decision on any application for Registration within two months of its receipt. In case the application can not be decided within two months, the Member-Secretary would record speaking reasons for the same and bring the case to the notice of CPCSEA at its ensuing meeting.

- (i) The application should be accompanied by a bank draft of Rs.1,000/- in favor of CPCSEA as registration fee.
- (ii) The establishment should have constituted an IAEC before applying for registration.
- (iii) Before taking the decision regarding Registration, a spot inspection of the organization would be necessary. The spot inspection would be carried out in the following manner:
 - (a) In case of Registration of an establishment for experiments on animals (under Rule 4 of Breeding Rules), the initial Inspection would be preliminary in nature, and carried out by one inspecting member. However, before conduct of experiments on animals specific approval regarding Animal House Facility will be necessary through inspection by a team constituted under para 6 (ii).
 - (b) In case of Registration of establishments for Breeding purposes (under Rule 3 of Breeding Rules), the spot Inspection would be carried out by the inspection team as constituted under para 6 (ii).

(ii) Approval of Animal House Facilities:

(a) Detailed inspection by a Inspection team. As per the existing practice the following is the composition of inspection team:

- (i) CPCSEA's Nominee
- (ii) Expert Consultant, CPCSEA
- (iii) Person in charge of another animal house in the same State, where the institution carrying out experiment is located. In the even of any constraint, from the adjoining State in the same region.

To ensure representation from all concerned sectors, the composition of the Inspection team is now proposed as below:

- (i) Expert Consultant, CPCSEA - Coordinator

- (ii) CPCSEA Nominee
- (iii) CPCSEA Nominee

The two CPCSEA Nominees should be so selected as to ensure balanced representation to address concerns both of veterinarians as well as those engaged in activities of Animal Welfare. Besides, a person in charge of some good Animal House Facility will be co-opted to assist the Inspection team.

The selection of members of the Inspection team including the co-opted member to assist the team, will be made from the approved panel.

Approval of Animal House Facility will be accorded by CPCSEA or by the Sub-Committee on Large Animals (SCLA), if so authorized.

(b) The time limit prescribed by the regulator should be adhered to even if one or two members of the team are not in a position to undertake the visit on scheduled date. In such case the Member-Secretary could substitute the members in the Inspection team from the approved panel, preferably from the same zone.

(iii) Permission of Committee for Conducting Experiments

- (a) No proposal for Animal Experimentation would be entertained, unless the Animal House Facility of the concerned establishment has been approved by competent authority.
- (b) The approval for experimentation on small animals will be accorded by IAEC.
- (c) Approval for experimentation on Large Animals will be considered by SCLA on the recommendation of IAEC.
- (d) The decision in the IAEC would normally be taken by consensus. If divergent views are expressed by the members these may be recorded in the minutes and a broad consensus be recorded as per understanding of the Chair. However, in case of dissent by the CPCSEA nominee, the proposal with the report of IAEC and the dissenting note of the CPCSEA nominee, would be submitted to SCLA for taking a final decision.
- (e) The decision in the SCLA would be taken by consensus. If divergent views are expressed by the members, these may be recorded in the minutes and a broad consensus be recorded as per understanding of the Chair.

7. Check-list for Standardized information:

(i) Registration of establishment for Breeding of animals & for experiments of animals:

- (i) Name and address of the Institute with telephone/fax numbers, as well as e-mail ID if available.
- (ii) Name and address of Head of the Institution
- (iii) Nature of activities
 - (a) Breeding purpose
 - (b) Experiment purpose
 (please tick the portion applicable)
- (iv) Layout plan of the establishment
- (v) Whether it is in line with the prescribed guidelines
- (vi) Whether there is any deviation from the prescribed Guidelines -Please mention.
- (vii) Present stock of animals – Species wise

Male	No.	
Female	No.	
- (viii) Source of procurement of Animals - Address of the supplier
- (ix) Whether animals have been supplied to other institute. If yes, details of Institutes for the last three years.
- (x) Availability of manpower – trained/untrained
- (xi) Purpose of registration

(ii) Permission of Committee for Conducting Experiments:

1. Name and address of the Institute with telephone/fax numbers, as well as e-mail ID if available.
2. Name and address of Head of the Institution
3. Registration number and date of registration
4. Project Title
5. Nature, purpose and justification of experiment to be undertaken
6. Source for procurement of animals
 - (a) Bred by establishment
 - (b) Procured from Breeder - mention Name, address and Registration number of breeder
 - (c) Procured from other legal source
 - (d) Are the records duly maintained
7. Place where the animals are presently kept (or proposed to be kept)
8. Place where the experiment is to be performed
9. Date on which the experiment is to commence and duration of experiment
10. Chief Investigator
 - (i) Name
 - (ii) Designation
 - (iii) Deptt/Div/Lab

- (iv) Telephone number
11. List of names of all individuals authorized to conduct procedures under this proposal.
 12. Funding Source
 13. Duration of the project
 - (i) Number of months
 - (ii) Date of initiation
 - (iii) Date of completion
 14. Study Objectives [the aims of study (and why they are important) to be explained briefly using non-technical terms as far as possible].
 15. Animals required
 - (i) Species
 - (ii) Age/Weight/Size
 - (iii) Gender
 - (iv) Numbers to be used (Year-wise breakups and total figures needed to be given)
 - (v) Number of days each animal will be housed
 16. Rationale for animal usage
 17. Why is animal usage necessary for these studies?
 18. Why are the particular species selected required?
 19. Why are the estimated number of animals essential?
 20. Similar experiments conducted in the past. If so, the number of animals used and results obtained in brief.
 - (i) If yes, why new experiment is required?
 21. Have similar experiment(s) been made by any other organization/agency? If so, their results in your knowledge.
 22. Description of procedures to be used
 23. Does the protocol prohibit use of anaesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection, or blood withdrawal)?

If yes, explanation and justification
 24. Will survival surgery be done?

If Yes, the following to be described

 - (i) List and description of all such surgical procedures (including methods of asepsis)

- (ii) Names, qualifications and experience levels of operators
- (iii) Description of post-operative care
- (iv) Justification if major survival surgery is to be performed more than once on a single individual animal

25. Care of Animals post-experimentation

26. Rehabilitation/Euthanasia (In case of euthanasia, justification for not undertaking rehabilitation and drug dosage and route for anesthesia, where appropriate, as well as methods of carcass disposal post experimentation).

27. Animal transportation methods if extra-institutional transport is envisaged

28. Use of hazardous agents
(Copy of IBC approval to be attached in case hazardous agents are used)

(iii) Format for Inspecting Teams for approval of Animal House Facilities for breeding of animals/conduct of experimentation on animals.

- (a) Details of animals, Species wise, kept at the time of Inspection in the Animal House
- (b) Veterinary Care of animals
- (c) Health status of animals
- (d) Animal Procurement
- (e) Quarantine, Stabilization and Separation
- (f) Physical Facilities
 - (i) Building materials
 - (ii) Corridor(s)
 - (iii) Utilities
 - (iv) Animal Room Doors
 - (v) Exterior windows
 - (vi) Floors
 - (vii) Drains
 - (viii) Walls and ceilings
 - (ix) Storage areas
 - (x) Facilities for sanitizing equipment and supplies
 - (xi) Experimental Area
 - (xii) Environment
 - (xiii) Temperature and Humidity control
 - (xiv) Ventilation
 - (xv) Power and lighting
 - (xvi) Noise control
- (g) Animal Husbandry
 - (i) Caging or housing system
 - (ii) Sheltered or outdoor housing
 - (iii) Social environment

- (h) Food
- (i) Bedding
- (j) Water
- (k) Sanitation and Cleanliness
- (l) Waste Disposal
- (m) Pest Control
- (n) Emergency, weekend and holiday care
- (o) Record keeping'
- (p) Personnel and Training
- (q) No. of technical staff, supporting staff, details of the training of the supporting staff
- (r) Transport of laboratory animals
- (s) Anaesthesia and Euthanasia
- (t) Laboratory animal ethics
- (u) Transgenic animals
- (v) Maintenance
- (w) Disposal
- (x) Details of rehabilitation facilities
- (y) Overall assessment
- (z) Recommendation (_____)

1. Recommended for approval (without any stipulations).

2. Recommended for approval with suggestions for improvement
(please specify here)

3. Recommended for fulfillment of stipulated conditions before
consideration for approval
(please specify here)

4. Recommended for rejection with specific grounds
(please specify here)

Member's Signature

Member's Signature

Member's Signature

Note : Please tick whichever is applicable.

8. Check Memo

(I) Registration :

	Date of action	
	Initiated	Completed
(a) Processing of application by Expert Consultant	<input type="checkbox"/>	<input type="checkbox"/>
(b) Inspection of the organization	<input type="checkbox"/>	<input type="checkbox"/>
(c) Approval of Member Secretary	<input type="checkbox"/>	<input type="checkbox"/>
(d) Conveying of decision to organization	<input type="checkbox"/>	<input type="checkbox"/>

(II) Clearance of proposal for conducting the experiment on large animals:

	Date of action	
	Initiated	Completed
(a) Approval of Animal House Facility		
(i) Inspection of animal house facility	<input type="checkbox"/>	<input type="checkbox"/>
(ii) Placing of Inspection Report before CPCSEA	<input type="checkbox"/>	<input type="checkbox"/>
(iii) Conveying the approval of facility to organization	<input type="checkbox"/>	<input type="checkbox"/>
(b) Approval of the Project Proposal		
(i) After approval of facility, placing of project proposal before SCLA	<input type="checkbox"/>	<input type="checkbox"/>
(ii) Conveying the decision of SCLA to institutes	<input type="checkbox"/>	<input type="checkbox"/>

9. Where specific guidelines have not been provided in forgoing provisions, the guidelines issued vide MOEF letter No. 20011/3/2002-GC dated 15th September, 2004 regarding observance of Good Practices in Environmental Regulation will be applicable (copy enclosed).
